

REMARKS

The present Office Action addresses claims 1-12 and 14-21, finding Applicant's previous reply filed May 31, 2006 not fully responsive for introducing claims to an invention independent or distinct from the invention originally claimed, and as such subject to withdrawal. Applicant amends claims 1-12 and 14-21.

By this amendment, claim 21 is amended to recite an intervertebral disc wall treatment device, and to remove recitations of intended use. Applicant believes these amendments are consistent with the substance of the interview conducted between the undersigned and Examiners Isabella and Chattopadhyay on March 21, 2006, and fully responsive to all outstanding rejections or objections.

Applicant respectfully requests reconsideration and withdrawal of all of the pending rejections in view of the amendments and the remarks presented below.

The previous Office Action, mailed March 6, 2006, addressed claims 1-12 and 14-21, rejected claims 18, 19, and 21 as being anticipated by Kuslich (U.S. Patent No. 5,571,189), and rejecting claims 18-21 as being unpatentable over Stubstad (U.S. Patent 3,867,728) as obvious. Claim 21 also stood rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claim 8 of U.S. Patent 6,997,956, this rejection having been obviated by the filing of a terminal disclaimer, which was approved by the Office on June 9, 2006. Applicant notes with appreciation the Examiner's previous indication that claims 1-12 and 14-17 contain allowable subject matter, and would be allowed if rewritten in independent form to include all of the limitations of the base claim and any intervening claims.

Applicant traverses the outstanding previous rejections, and amends all of the claims.

By this amendment, all of the claims are amended to recite an intervertebral disc wall treatment device (*i.e.*, an apparatus), and to remove recitations of intended use. Independent claim 21 also recites means for acute securement of the device to the annulus. Support for this limitation can be found throughout the specification, and specifically at paragraph nos. [012], [014], [041], [042], [045], [046], and [059] to [061] of the publication of this application, or U.S. Publication No. 2002/0123807. Among other things, the cited paragraphs disclose the use of various fixation devices for acute securement of the therapeutic or prophylactic device to the annulus fibrosus. Accordingly, no new matter is added by these amendments.

Applicants respectfully request reconsideration and withdrawal of all of the pending rejections in view of the amendments and the following remarks.

The Prior Art Rejections

The previous Office Action rejected claims 1-12 and 14-21, rejecting claims 18, 19, and 21 under 35 U.S.C. §102(b) as anticipated by Kuslich (U.S. Patent No. 5,571,189), and claims 18-21 as being unpatentable over Stubstad (U.S. Patent 3,867,728) under 35 U.S.C. § 103(a) as obvious . For the following reasons, Applicant requests reconsideration and withdrawal of the rejections.

Rejection under 35 U.S.C. § 102(b) over Kuslich

As amended, independent claim 21 requires means for acute securement of said device to said disc annulus. This limitation is neither taught nor suggested by Kuslich.

Nowhere does Kuslich teach any steps whatsoever for acutely securing the device **120** to the disc annulus, as is required of the claimed method. Accordingly, since Kuslich fails to disclose or suggest each and every limitation of the claimed invention, Applicant respectfully requests reconsideration and withdrawal of the rejections of claims 18, 19, and 21 over Kuslich in view of the amendment.

Rejection under 35 U.S.C. § 103(a) over Stubstad

As amended, independent claim 21 requires means for acute securement of said device to said disc annulus. This limitation is neither taught nor suggested by Stubstad.

Nowhere does Stubstad teach a spinal disc treatment device, nor any means for acutely securing his nuclear replacement device **120** to the disc annulus, as is required by the claimed method. The Examiner points to Stubstad's teaching of securing the nuclear replacement device to "other available tissues" as evidence that annular fixation would be obvious. Applicant disagrees.

Stubstad describes the negative effects of lateral stresses on the nuclear replacement disc after implantation. See col. 3, ll. 29-63. Stubstad also teaches providing a sidewall promoting the sealing of the rupture site in the posterior portion of the annulus fibrosus. Col. 13, ll. 19-23. Stubstad does not teach or suggest suturing the nuclear replacement to the annulus itself. Because the nuclear replacement requires attachment to at least one vertebra as discussed throughout Stubstad, and

concomitant movement therewith, suturing the disc replacement to the annulus fibrosus would transfer large dynamic stresses on the annular wall, which would be concentrated at the point of suturing. The result of such suturing could be tearing of the annulus. In light of this observation, which would be obvious to one having ordinary skill in the art, it is respectfully submitted that one reading the Stubstad patent would not understand it to teach such a practice. The specification passage referenced by the Examiner, Col. 14, ll 48-50, recites:

The two segments [121, 122] may be further stabilized by tying them together by cords 129 or by suturing to one of the adjacent vertebrae or other available tissue.

It is respectfully submitted that Stubstad's reference to "tissue" does not explicitly include annular tissue, but rather refers to other tissue in the vicinity of the disc, as set forth at Col. 2, ll. 45-48:

This simple prosthetic disc is retained in place by reconstructed natural tissue surfaces, such as the cortical plate of the vertebral bodies, and the anterior and posterior longitudinal ligaments.

Accordingly, since Stubstad fails to teach or suggest the claimed invention, Applicant respectfully requests reconsideration and withdrawal of the rejections of claims 18-21 over Stubstad.

Double Patenting Rejection

The Rejection of claim 21 has been obviated by the filing of a terminal disclaimer, which was accepted by the Office on June 9, 2006. It is respectfully requested that the rejection be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims. Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Date: September 18, 2006

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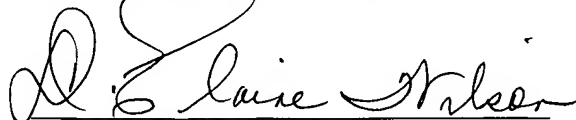
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By:



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